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Our Docket No. CMCC 779
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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Samy Ashkar and Jairo Salcedo

Serial No.: 09/981,845 Art Unit: 1647

Filed: October 18, 2001 Examiner: Regina M. Deberry

For: *OSTEOPONTIN-COATED SURFACES AND METHODS OF USE*

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Application Number	09/ 981,845
Filing Date	October 18, 2001
First Named Inventor	Samy Ashkaar
Art Unit	1647
Examiner Name	Regina M. Deberry
Attorney Docket Number	CMCC 779

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
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- [ ] Amendment/Reply
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3 references-2 papers and 1 abstract

Remarks

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Date	December 2, 2004

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Effective 10/01/2004. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

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Complete if Known	
Application Number	09/981,845
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Attorney Docket No.	CMCC 779

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1003	550	2003	275	Plant filing fee	
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Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	44	Independent claims in excess of 3
1203	300	2203	150	Multiple dependent claim, if not paid
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1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

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1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	0.00
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
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1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
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Serial No.: 09/981,845 Art Unit: 1647

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For: *OSTEOPONTIN-COATED SURFACES AND METHODS OF USE*

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SUBSTITUTE APPEAL BRIEF

Sir:

Responsive to the Notification of Non-Compliance with 37 C.F.R. 1.192(c) mailed on November 18, 2004, this is a substitute Appeal Brief to replace the Appeal Brief filed on August 16, 2004. This is an Appeal from the final rejection of claims 1-6 in the Office Action mailed February 13, 2004, in the above-identified patent application. A Notice of Appeal was mailed on June 14, 2004 (there is an error in the Advisory Action mailed June 28, 2004). In the Appeal Brief filed on August 16, 2004, the Commissioner was authorized to charge $165.00, the fee for the filing of this Appeal Brief for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is Children's Medical Center Corporation in Boston, MA, the assignee of record; and the licensee of record OraPharma, Inc. in Warminster, PA.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 1-6 are pending. Claims 1-6 are on appeal. Claims 7-18 were cancelled in an Amendment filed on November 21, 2003. The text of each claim on appeal, as pending, is set forth in an Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

An amendment after final rejection was mailed on May 11, 2004. In the Advisory Action mailed June 28, 2004, the Examiner indicated that this amendment would be entered. An appendix sets forth the claims on appeal.

(5) SUMMARY OF THE INVENTION

The claims are drawn to isolated active osteopontin fragments and osteopontin-derived peptide fragments that have cell-attachment and cell-spread activity (page 7, line 23 to page 8, line 12). The peptide fragments may be used to increase cell attachment to a material, as well as enhance cell spread on the material (page 11, lines 9-18). The material is suitable for use on a

material which is implanted into a patient to enhance cell-attachment and cell-spread activity and thereby integration of the implant, for example, for use in treatment of periodontal disease (page 10, lines 16-23). Claim 1 is directed to an osteopontin-derived peptide fragment comprising an amino acid sequence selected from the group consisting of SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, and SEQ ID NO:15 (page 8, lines 7-26 and page 12, lines 4-13). Claim 2 is directed to the peptide fragment of claim 1, wherein the peptide increases cell attachment to a material and increases cell spread (page 8, lines 11-12 and page 53, lines 12-17). Claim 3 is directed to the peptide fragment of claim 2, wherein the peptide binds to at least one receptor on a cell surface. Claim 4 is directed to the peptide fragment of claim 3, wherein the receptor(s) is an integrin. Claim 5 is directed to the peptide fragment of claim 4, wherein the integrin(s) is $\alpha_v\beta_3$, $\alpha_v\beta_5$, $4\beta_1$, $2\beta_1$, VCAM, ICAM CD44, or V_3V_x. Support for claims 3, 4, and 5 can be found on page 3, line 27 to page 4, line 14 and page 53, lines 17-21. Claim 6 is directed to the peptide fragment of claim 3 wherein the cell is an osteoprogenitor cell, tumor cell, macrophage, periosteal cell, endothelial cell, epithelial cell, eosinophil, stem cell, limited potential precursor cell, precursor cells committed precursor cell, or differentiated cell (page 8, line 29 to page 9, line 2).

(6) ISSUES ON APPEAL

The issues presented on appeal are:

(1) whether claims 1-6 are enabled under 35 U.S.C. § 112, first paragraph.

(7) GROUPING OF CLAIMS

The claims do not stand or fall together. Arguments for the separate patentability of the claims are provided below.

(8) ARGUMENTS

(a) The Claimed Invention

The claims are directed to active osteopontin-derived peptide fragments and their use in and/or on materials to increase cell attachment and cell spread activity. The peptides may be used to coat, for example, a surgical implant where cell attachment and growth on the implant are desirable. The peptide fragments comprise the sequences VFTPVVPTVDTYDGRGDSVVYGLRSKSKKFRRP (SEQ ID NO. 7), RSRRATEVFTPVVPTVDTYDGRGDSVVYGLRSKSKKFRRP (SEQ ID NO:8), SDELVTDFPTDLPATEVFTPVVPTVDTYDGRGDSVVYGLRSKSKKFRRP (SEQ ID NO:9), RSRRATEVFTPVVPTVDTYDGRGDSVVYGRRSKSKKFRRP (SEQ ID NO:10), RSRRATEVFTPVVPTVDTYDGRGDSVVYGRRSKSKKFRRPAGAAGGPAGPAG PAGPAGPAGPA (SEQ ID NO:11), RSRRVFTPFIPTESANDGRGDSVAYGLKSKSKKFRR (SEQ ID NO:12), DTFTPIVPTVDVPNGRFDSLAYGLKSKSKKFQ (SEQ ID NO:13), RSRRATEVFTPVVPTVDTYDGRADSVVYGRRSKSKKFRRP (SEQ ID NO:14), and acetyl-RSRRATEVFTPVVPTVDTYDGRGDSVVYGLRSKSKKFRRP (SEQ ID NO:15).

The osteopontin-derived peptide fragments increase cell binding and spread by binding to integrins, such as $\alpha_v\beta_3$, $\alpha_v\beta_5$, $4\beta_1$, $2\beta_1$, VCAM, ICAM CD44, V_3V_x, on the surface of cells. The peptide fragments may be used to modulate a number of different cell types, including

osteoprogenitor cells, tumor cells, macrophages, periosteal cells, endothelial cells, epithelial cells, eosinophils, stem cells, limited potential precursor cells, precursor cells, committed precursor cells, and differentiated cells.

The peptides have numerous applications, but principally in tissue repair or regeneration, for example, when coated onto a titanium material and used in the treatment of periodontal disease to enhance bone regrowth.

(b) Rejection of claims 1-6 Under 35 U.S.C. § 112, first paragraph

The Legal Standard

The Court of Appeals for the Federal Circuit (CAFC) has described the legal standard for enablement under § 112, first paragraph, as whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art as of the date of filing, without undue experimentation (*See, e.g., Amgen v. Hoechst Marion Roussell* 314 F.3d 1313 (Fed. Cir. 2003; *Genentech, Inc. v. Novo Nordisk A/S*, 108 F3d at 165, 42 USPQ2d at 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *In re Fisher*, 427 F.2d at 839, 166 USPQ at 24; *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343 (CCPA 1976)). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (*M.I.T. v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985)). As affirmed by the Court in *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987), a patent need not teach, and preferably omits, what is well known in the art.

Whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See *In re Wands*, 858 F.2d 731, 735, 736-737, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir.1988). As set forth in *Wands*, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. In cases that involve unpredictable factors, "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive.' *Atlas Powder Co., v. E.I. DuPont De Nemours & Co.* , 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir.1984). There is no requirement for examples.

Analysis

A proper analysis of the *Wands* factors shows that claims 1-6 satisfy the enablement requirement. The quantity of experimentation necessary to make and use the claimed peptides is **not undue.** The claims are directed to ostepontin-derived peptide fragements comprising SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, or SEQ ID NO:15. These sequences are well described and characterized. The amino acid sequence and structure of osteopontin, from which the peptide

fragments are derived, are well known. One skilled in the art would have no difficulty making short peptides or longer peptides, synthetically, using a portion of the nucleotide sequence encoding osteopontin, as recited in claim 1. The point of novelty is the identification of the amino acid sequence in a very large protein which has the desired activity, and that this activity is retained even in a very small peptide relative to the huge protein from which it is derived. The specification describes how to coat the peptides to a material (page 13, line 14 to page 14, line 21) and describes the types of materials that may be coated (page 10, lines 16-23 and page 14, lines 22-28).

The specification also describes a number of cell types that may be regulated using the osteopontin-derived peptides fragments (page 8, line 29 to page 9, line 2). Although there is no requirement for examples, Example 12 and Table 8 on pages 53-55 demonstrate that each of SEQ ID NO:15, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, or SEQ ID NO:14 binds to osteoprogenitor cells and significantly increases cellular attachment and spread over the control. In addition, the specification teaches that the peptides bind receptors on the surface of cells (page 3, line 27 to page 4, line 14), and Example 12 and Table 8 illustrate that the peptides interact with integrins, as shown by the ability of anti-integrin antibodies to inhibit the percentage of attached cells and cell spread induced by the peptides (i.e., SEQ ID NO: 15).

Integrins are the principal receptors on animal cells for binding most extracellular matrix proteins, including collagen, fibronectin, and laminin. They are found on the surface of numerous cell types (see, for example, *Molecular Biology of the Cell*. IV. Cells in Their Social

Context. 19. Cell Junctions, Cell Adhesion, and the Extracellular Matrix, Garland Publishing (1994)). Although the specification uses osteoprogenitor cells as an example, one of ordinary skill in the art would know that the claimed osteopontin-derived peptide fragments would interact with integrins found on diverse cell types. Osteopontin, itself, interacts with a number of different cell types (page 2, lines 23-25).

Therefore, it is clear that claim 2, which recites that the peptide increases cell attachment to a material and increases cell spread is enabled. Because of the ubiquitous expression of integrins in cells, the amount of experimentation necessary to use the osteopontin-derived fragments to increase the attachment and spread of other cell types, such as those recited in claim 6, is not undue. In addition, claim 3, which recites that the peptides bind to at least one receptor on a cell surface, and claim 4, which specifies that the receptor is an integrin, are clearly enabled by the specification and examples.

Furthermore, the guidance in the specification and ease in carrying out the assays, as shown in the examples, clearly enables one to culture plates with any type of cell expressing different receptor/integrin molecules, and assay for cell attachment and/or cell spread in the presence or absence of the claimed peptides. One of ordinary skill in the art is also enabled to identify other peptides exhibiting the claimed activities. As demonstrated in Example 12, plates can be coated with any of the osteopontin-derived peptide fragments and cultured with cells. The percent increase in cell attachment and cell spread are readily measured by methods commonly used in the art. One then may add antibodies to different integrins, such as those recited in claim 5 ($\alpha_v\beta_3$, $\alpha_v\beta_5$, $4\beta_1$, $2\beta_1$, VCAM, ICAM CD44, V_3V_X), to see if osteoponin-

peptide-induced cell attachment and spread is attenuated and to determine which of the integrins are important for the effects of the osteopontin-derived peptide fragments in a particular cell type. Anti-integrin antibodies may be produced or obtained from many commercial suppliers or laboratories.

The Examiner alleges that the data demonstrating the binding of SEQ ID NO: 15 to $\alpha_v\beta_3$ in Table 8 cannot be extrapolated to the elected species, SEQ ID NO: 11, or any other osteopontin derived peptide binding any integrin on any cell type, because SEQ ID NO: 15 was still able to cause human osteoprogenitor cells to attach and spread in the presence of antibodies against CD44 and $\alpha\beta_1$. However, just because the antibodies against CD44 and $\alpha\beta_1$ failed to inhibit cell attachment and spreading does not mean that the peptide does not bind to these particular receptors. It most likely means that CD44 and $\alpha_v\beta_1$ are either weakly expressed or not expressed by osteoprogenitor cells and/or peptide-induced cell migration and cell spread in osteoprogenitor cells preferentially occurs through a specific integrin or integrins (i.e., $\alpha_v\beta_3$) other than CD44 and $\alpha\beta_1$. See, for example, Noonan KJ et al. J. Orthop Res. 14(4): 573-81 (1996) (abstract attached), which describes that reduced expression of CD44 was observed in osteoprogenitor cells compared to other bone-related cell types.

In addition, other integrins besides $\alpha_v\beta_3$ may modulate cell attachment and cell spread activity in different cell types. See, for example, Tuck et al. J. Cell Biochem 78(3): 465-475 (2000) (attached), which describes the osteopontin-induced migration of several mammary epithelial cell lines. The study demonstrates that the spread of one of the cell lines was $\alpha_v\beta_5$ and β_1-integrin dependent, but $\alpha_v\beta_3$-independent, while that of another cell line was $\alpha_v\beta_3$-dependent.

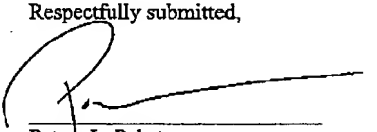
Therefore, even though it is well known that osteopontin binds to $\alpha_v\beta_3$ (Hu et al. J. Biol. Chem. 270 (44): 26232-26238 (1995) (attached)), antibodies to this integrin would not block the osteopontin-induced migration of the first cell line. Likewise, it appears that osteopontin-derived peptide fragment-induced attachment and spread of osteoprogenitor cells is mediated through $\alpha_v\beta_3$ and not CD44, even though the peptide fragments may bind to CD44. There is no legal requirement, however, that the claimed peptides bind all integrins or to all cell types for the peptides to have the specified utility.

(9) SUMMARY AND CONCLUSION

The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988). It is clear from the direction or guidance given by the specification, the presence of working examples, the state of the prior art and the relative skill of those in the art, that one of ordinary skill in the art could make and use the claimed osteopontin-derived peptide fragments to increase cell attachment to a material. In addition, one is clearly enabled to test for the ability of the claimed peptide fragments to bind to integrin receptors on the surface of any cell type.

For the foregoing reasons, Appellants submit that claims 1-6 are enabled.

Respectfully submitted,



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